

REMARKS

I. STATUS OF CLAIMS

Claims 1-43 are pending in this application. No amendments are made by this Reply.

II. REJECTIONS UNDER 35 U.S.C. § 103

A. Zawistowski

The Office rejected claims 1-24 and 32-43 under 35 U.S.C. § 103(a) as unpatentable over WO 00/45648 to Zawistowski ("Zawistowski"). Office Action at page 2. According to the Office, Zawistowski teaches a method of preparing microparticles of phytosterols and phytostanols with a particle size preferably at 100 microns. *Id.* The Office particularly points Applicants to Example 1 directed to a yoghurt preparation, but admits that Zawistowski differs from the present invention with regard to the particle size of the starting material. *Id.* at page 3. The Office, moreover, provides that the limitations in certain dependent claims directed to particle size of the starting material, and other limitations in certain dependent claims, *e.g.*, low treatment pressure, viscosity and particle size distribution, do not provide for unobvious or unexpected results seen from the composition. *Id.* According to the Office, the present invention is obvious in view of Zawistowski. *Id.* Applicants respectfully disagree and traverse the rejection for the following reasons.

As described in Applicants' specification at pages 5 and 6, Zawistowski describes a method for preparing microparticles of plant sterols and stanols by:

- (1) dispensing and suspending the sterols and/or stanols in a semi-fluid, fluid or viscous vehicle; and then,

- (2) exposing the vehicle to impact forces, i.e., high shear forces.

Zawistowski at [0018] - [0021]. These impact forces can be created by using an air-atomization nozzle, a pneumatic nozzle, a *high shear mixer* or colloid mill, or a microfluidizer. *Id.* at [0021].

As recited in, e.g., claim 1, the process of the present invention comprises “mixing the at least one hydrophobic plant sterol with said aqueous material to form a first dispersion of particles of the at least one hydrophobic plant sterol and said aqueous material” As exemplified in Example 1 of the present specification, “the mixture [of plant sterol and orange juice concentration as the aqueous material] was blended using an Arde-Barino Model No. CJ-4 *high shear mixer* at 7000 rpm for about 15 minutes to produce a first dispersion” Applicants’ Specification at [074] (emphasis added). The present invention contemplates an additional step: “homogenizing the first dispersion in an APV homogenizer, Model No. APV 1000 from the APV Homogenizer Group (an Invensys Company) at 2,500 psi and then at 500 psi produced the second dispersion.” *Id.* at [075]. But, Zawistowski teaches that mixing with a high shear mixer to form the first dispersion of the present invention qualifies as an “impact force,” and as such, fails to teach/suggest further physical manipulation and particularly, homogenization.

In fact, Zawistowski teaches at [0031] that

[t]he microparticle phytosterol and/or phytostanols so formed may be used *without further modification or adaptation and incorporated directly* into foods, beverages, nutraceuticals and pharmaceuticals or, alternatively may be further treated (e.g., esterified and/or hydrogenated) and/or *formed into other delivery vehicles* such as emulsions, microemulsions, liposomes, hydrated lipid systems, cyclodextrin or bile acid complexes and the like prior to such incorporation.

Zawistowski at [0031] (emphasis added).

These teachings clearly do not provide for any further physical manipulation and surely, do not specifically teach homogenizing the dispersion, as recited in the presently rejected claims. Without such teachings, Zawistowski does not teach all the claim limitations and as such, fails to establish a *prima facie* case of obviousness. M.P.E.P. § 2143. Accordingly, Applicants respectfully request the withdrawal of the rejection.

B. Yoon

The Office also rejected claims 1-43 under 35 U.S.C. § 103 as unpatentable over U.S. Patent Application Publication No. 2002/0064548 to Yoon ("Yoon"). Office Action at page 4. According to the Office, Yoon teaches a dispersed plant sterol in an aqueous phase, which is then added to a beverage. *Id.* Further, Yoon's process entails mixing the plant sterol with an emulsifier and then heating to 200°C, which is then mixed using high speed stirring and homogenization. *Id.* The Office, however, admits Yoon does not provide for the particle size of the starting materials, but asserts that no unobvious or unexpected results are seen from the selection of particular particle size. *Id.* Under the Office's rationale, other differences in viscosity, particle size distribution, and the use of citrus beverages recited in the dependent claims are also dismissed as providing no unobvious or unexpected results. *Id.* As such, the Office concludes that the present invention recited in the pending claims would have been obvious in view of Yoon. *Id.* Applicants respectfully disagree and traverse the rejection for the following reasons.

Yoon is directed to "a method of dispensing plant sterols into *micelles* with a size of hundreds of nanometers, which improves the bioavailability of sparingly soluble plant sterols, has proper dose proportionality, and shows a maximum of dispersion stability."

Yoon at [0032] (emphasis added). In particular, Yoon's method comprises:

1. admixing plant sterol with an *emulsifier*;
2. melting the admixture by heating at 60 - 200°C;
3. mixing the molten substance with an aqueous beverage; and
4. stirring the mixture at high speed to give a dispersion of plant sterols.

Id. at [0033] (emphasis added).

Emulsifiers used in Yoon's process include "sucrose fatty acid ester, sorbitan fatty acid ester, polyglycerol fatty acid, propylene glycerol fatty acid, and polyglycine fatty acid ester," which do not denature at 60°C. *Id.* at [0036]. Although Yoon provides various embodiments of micellular formation, micelle formation is nonetheless required by melting the emulsifier and sterol together. See *id.* at [0044], [0045], and [0046]. Accordingly, Yoon's solution to the solubility problem of plant sterols is to teach micellular formation of sterols with emulsifiers, *i.e.*, the use of a delivery vehicle.

In contrast, "the process of the invention and resultant composition does *not* require the use of *gums and/or emulsifiers* in order to obtain a stable dispersion of the plant sterols in the aqueous material without separation, flavor impact and texture impact" Applicants' specification at [020] (emphasis added). For example, independent claim 1 recites:

mixing the at least one hydrophobic plant sterol with said aqueous material to form a first dispersion of particles of the at least one hydrophobic plant sterol and said aqueous material;
homogenizing the first dispersion to obtain a second dispersion of particles of the at least one hydrophobic planter sterol and said aqueous material
. . .

There is no requirement of the inclusion of "emulsifiers" in these process steps to generate a vehicle to deliver the sterol/stanol. It, moreover, would run counter to the

teachings in the specification, as detailed above and further provided at page 11 at [031] and page 14 at [036]. "Manufacturing aids," however, may be employed in the present invention, e.g., to bring the viscosity of the beverage into the recited ranges. See Applicants' Specification at [032]. Thus, Yoon's teachings directed to producing a delivery vehicle for the sterol, *i.e.*, requiring an emulsifier to generate micelles of phytosterols, teach away from mixing and homogenizing the sterol in an aqueous medium. As provided in M.P.E.P. § 2145 (X)(D)(1), "a prior art reference that 'teaches away' from the claimed invention is a *significant factor* to be considered in determining obviousness." M.P.E.P. § 2145 (emphasis added).

Accordingly, Applicants respectfully request the withdrawal of the rejection.

C. Rogers

The Office also rejected claims 1-24 and 32-43 under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 6,391,370 to Rogers ("Rogers"). Office Action at page 5. In particular, the Office contends that Rogers teaches treating phytosterols with an emulsifier and melting the result, which is later milled to a particle size of about 10 microns. *Id.* Again, the Office notes that differences in particle size of the starting material, viscosity, and a particle size of a bell shaped curve do not provide for any unobvious or unexpected results. *Id.* Accordingly, the Office surmises that the present invention as recited in the rejected claims is obvious in view of Rogers. *Id.* Applicants respectfully disagree and traverse the rejection for the following reasons.

Rogers, like Yoon, requires emulsifiers. For example, Rogers teaches that "to form the desired aqueous plant sterol dispersion, the plant sterol is mixed with an *emulsifier* in a water solvent to form a coarse dispersion and then the coarse dispersion

is micromilled at, close to, or below ambient temperature to form the desired plant sterol dispersion having an average plant sterol particle size of 1 to about 40 microns.”

Rogers at Col. 7, ll. 21-26 (emphasis added). Suitable micromilling techniques and equipment include ball mills, horizontal media mills, ring mills, colloid mills, and the like. *Id.* at Col. 9, ll. 38-46. As such, Rogers’ teachings of the required use of emulsifiers is inapposite to the presently recited claims, which lack the recitation of an emulsifier, and run contrary to teachings in the specification as detailed above with regard to the Yoon rejection.

Rogers, moreover, fails to teach a homogenization step and/or fails to teach that micromilling is equivalent to homogenization. In fact, it is recognized in the art that milling techniques are “cumbersome, expensive and because dry milling generates high energy, the produced particles could form aggregates. In addition, producing uniform particle size distribution below 10 μm is difficult, if not impossible, using these conventional techniques.” Zawistowski at [0015].

Lacking sufficient teachings, Rogers cannot establish a *prima facie* case of obviousness. M.P.E.P. § 2143. Thus, Applicants respectfully request the withdrawal of the rejection.

III. DOUBLE PATENTING

The Office has also rejected claims 1-43 under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 1-117 of copending U.S. Patent Application No. 10/458,692. Office Action at page 6. The Office admits that although the claims are not identical, they are not patentably distinct from

each other. *Id.* While Applicants respectfully disagree, Applicants submit herewith a Terminal Disclaimer over this copending application in order to advance prosecution.

IV. CONCLUSION

In view of the foregoing remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.


If the Examiner believes that a telephone conference could be useful in resolving any outstanding issues, she is respectfully urged to contact Applicants' undersigned counsel at 202.408.4345.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

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